



RULE-MAKING ORDER

CR-103P (May 2009)
(Implements RCW 34.05.360)

Agency: Department of Health- Medical Quality Assurance Commission

Permanent Rule Only

Effective date of rule:

Permanent Rules

☐ 31 days after filing.

☒ **Other (specify)** 01/02/2012 (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes

☒ No

If Yes, explain:

Purpose: ESHB 2876 (chapter 209, Laws of 2010) directs the Medical Quality Assurance Commission to repeal existing pain management rules and adopt new rules for the management of chronic noncancer pain. The adopted rules include the mandatory elements for dosing criteria, guidance on specialty consultants, guidance on tracking clinical progress, and guidance on tracking opioid use. The adopted rules also describe practitioner consultation exemptions.

Citation of existing rules affected by this order:

Repealed: WAC 246-919-800, 810, 820, and 830

Amended: None

Suspended: None

Statutory authority for adoption: RCW 18.71.450, RCW 18.71A.100, RCW 18.71.017, RCW 18.71A.020

Other authority :

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 11-03-063 on 01/18/2011 (date).

Describe any changes other than editing from proposed to adopted version: See Attachment A.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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Date adopted: 03/04/2011

NAME (TYPE OR PRINT)

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CODE REVISER USE ONLY

**OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED**

DATE: May 24, 2011

TIME: 2:26 PM

WSR 11-12-025

(COMPLETE REVERSE SIDE)

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>28</u>	Amended	<u>0</u>	Repealed	<u>4</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in the agency's own initiative:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>28</u>	Amended	<u>0</u>	Repealed	<u>4</u>

Pain Management Rules Attachment A

Language Changes:

The adopted rules include the following changes from the proposed rules published as WSR 11-03-063.

- Pain management—Intent – WAC 246-919-850 and WAC 246-918-800. Language is added to clarify the commission's intent and philosophy for the rules.
In WAC 246-918-800 language is added to clarify that these rules do not restrict the current scope of practice for the physician assistant or the working agreement between the physician assistant and the physician, which may include pain management.
- Definitions – WAC 246-919-852 and 246-918-802
 - The terms "Episodic care," "Morphine equivalent dose", and "Multidisciplinary pain clinic" are added to the definitions.
 - The terms "Physical dependence," "Psychological dependence," and "Tolerance" are deleted as these terms are not used in the rules.
- Written agreement for treatment – WAC 246-919-856(4) and 246-918-806(4). "or multidisciplinary pain clinic" and "or pharmacy system" are added.
- Long-acting opioids, including methadone – WAC 246-919-858 and 246-918-808. In the third sentence, after "one-time", "(lifetime)" is added.
- Consultation: Recommendations and requirements – WAC 246-919-860(1) and WAC 246-918-810(1). The words "and document the consideration" are added to clarify that the physician and physician assistant must also document the consideration to refer a patient.
- Consultation: Recommendations and requirements – WAC 246-919-860(2) and 246-918-810(2). The word "adult" is added to clarify the morphine equivalent dose (MED) threshold is for adults. The word "oral" is also added to clarify that the threshold is based on an "oral" dose. Language regarding pediatric patients is also added at the end of the paragraph: "Great caution should be used when prescribing opioids to children with chronic noncancer pain and appropriate referrals to a specialist is encouraged."
- Pain management specialist – WAC 246-919-863(1)(d)(ii) and 246-918-813(1)(d)(ii). Language is added to clarify the cycle in which to complete the required continuing education is two years for physicians and three years for osteopathic physicians.
- Pain management specialist – WAC 246-919-863(1)(d)(iii) and (3)(d) and 246-918-813(1)(d)(iii) and (3)(d). Language is added to clarify that the current practice may also be in a multidisciplinary pain clinic setting.

The adopted rules also include edits for grammar, punctuation, and formatting.

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 246-919-800	Purpose.
WAC 246-919-810	What specific guidance should a practitioner follow?
WAC 246-919-820	What knowledge should a practitioner possess to treat pain patients?
WAC 246-919-830	How will the commission evaluate prescribing for pain?

Pain Management

NEW SECTION

WAC 246-919-850 Pain management--Intent. These rules govern the use of opioids in the treatment of patients for chronic noncancer pain.

The Washington state medical quality assurance commission (commission) recognizes that principles of quality medical practice dictate that the people of the state of Washington have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this rule, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this rule has been developed to clarify the commission's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from a physician's lack of knowledge about pain management. Fears of investigation or sanction by federal, state, and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the commission will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The commission recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or

noncancer origins. The commission will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and nonpharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The commission is obligated under the laws of the state of Washington to protect the public health and safety. The commission recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the commission expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the commission for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The commission will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The commission will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

These rules are designed to assist practitioners in providing appropriate medical care for patients. They are not inflexible rules or rigid practice requirements and are not intended, nor should they be used, to establish a legal standard of care outside the context of the medical quality assurance committee's jurisdiction.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner based on all the circumstances presented. Thus, an approach that differs from the rules, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary,

a conscientious practitioner may responsibly adopt a course of action different from that set forth in the rules when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of these rules. However, a practitioner who employs an approach substantially different from these rules is advised to document in the patient record information sufficient to justify the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these rules will not assure an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist practitioners in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

NEW SECTION

WAC 246-919-851 Exclusions. The rules adopted under WAC 246-919-850 through 246-919-863 do not apply:

- (1) To the provision of palliative, hospice, or other end-of-life care; or
- (2) To the management of acute pain caused by an injury or surgical procedure.

NEW SECTION

WAC 246-919-852 Definitions. The definitions in WAC 246-919-850 through 246-919-863 apply unless the context clearly requires otherwise.

(1) "Acute pain" means the normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease. It is generally time-limited, often less than three months in duration, and usually less than six months.

(2) "Addiction" means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is

characterized by behaviors that include:

- (a) Impaired control over drug use;
- (b) Craving;
- (c) Compulsive use; or
- (d) Continued use despite harm.

(3) "Chronic noncancer pain" means a state in which noncancer pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

(4) "Comorbidity" means a preexisting or coexisting physical or psychiatric disease or condition.

(5) "Episodic care" means medical care provided by a practitioner other than the designated primary care practitioner in the acute care setting, for example, urgent care or emergency department.

(6) "Hospice" means a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less. Hospice involves an interdisciplinary approach to provide health care, pain management, and emotional and spiritual support. The emphasis is on comfort, quality of life and patient and family support. Hospice can be provided in the patient's home as well as freestanding hospice facilities, hospitals, nursing homes, or other long-term care facilities.

(7) "Morphine equivalent dose" means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.

(8) "Multidisciplinary pain clinic" means a clinic or office that provides comprehensive pain management and includes care provided by multiple available disciplines or treatment modalities, for example, medical care through physicians, physician assistants, osteopathic physicians, osteopathic physician assistants, advanced registered nurse practitioners, and physical therapy, occupational therapy, or other complementary therapies.

(9) "Palliative" means care that improves the quality of life of patients and their families facing life-threatening illness. With palliative care particular attention is given to the prevention, assessment, and treatment of pain and other symptoms, and to the provision of psychological, spiritual, and emotional support.

NEW SECTION

WAC 246-919-853 Patient evaluation. The physician shall obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for chronic noncancer pain.

- (1) The patient's health history shall include:
 - (a) Current and past treatments for pain;

- (b) Comorbidities; and
- (c) Any substance abuse.
- (2) The patient's health history should include:
 - (a) A review of any available prescription monitoring program or emergency department-based information exchange; and
 - (b) Any relevant information from a pharmacist provided to a physician.
- (3) The initial patient evaluation shall include:
 - (a) Physical examination;
 - (b) The nature and intensity of the pain;
 - (c) The effect of the pain on physical and psychological function;
 - (d) Medications including indication(s), date, type, dosage, and quantity prescribed;
 - (e) A risk screening of the patient for potential comorbidities and risk factors using an appropriate screening tool. The screening should address:
 - (i) History of addiction;
 - (ii) Abuse or aberrant behavior regarding opioid use;
 - (iii) Psychiatric conditions;
 - (iv) Regular concomitant use of benzodiazepines, alcohol, or other central nervous system medications;
 - (v) Poorly controlled depression or anxiety;
 - (vi) Evidence or risk of significant adverse events, including falls or fractures;
 - (vii) Receipt of opioids from more than one prescribing practitioner or practitioner group;
 - (viii) Repeated visits to emergency departments seeking opioids;
 - (ix) History of sleep apnea or other respiratory risk factors;
 - (x) Possible or current pregnancy; and
 - (xi) History of allergies or intolerances.
- (4) The initial patient evaluation should include:
 - (a) Any available diagnostic, therapeutic, and laboratory results; and
 - (b) Any available consultations.
- (5) The health record shall be maintained in an accessible manner, readily available for review, and should include:
 - (a) The diagnosis, treatment plan, and objectives;
 - (b) Documentation of the presence of one or more recognized indications for the use of pain medication;
 - (c) Documentation of any medication prescribed;
 - (d) Results of periodic reviews;
 - (e) Any written agreements for treatment between the patient and the physician; and
 - (f) The physician's instructions to the patient.

NEW SECTION

WAC 246-919-854 Treatment plan. (1) The written treatment plan shall state the objectives that will be used to determine treatment success and shall include, at a minimum:

- (a) Any change in pain relief;
- (b) Any change in physical and psychosocial function; and
- (c) Additional diagnostic evaluations or other planned treatments.

(2) After treatment begins the physician should adjust drug therapy to the individual health needs of the patient. The physician shall include indications for medication use on the prescription and require photo identification of the person picking up the prescription in order to fill. The physician shall advise the patient that it is the patient's responsibility to safeguard all medications and keep them in a secure location.

(3) Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

NEW SECTION

WAC 246-919-855 Informed consent. The physician shall discuss the risks and benefits of treatment options with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without health care decision-making capacity.

NEW SECTION

WAC 246-919-856 Written agreement for treatment. Chronic noncancer pain patients should receive all chronic pain management prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse, or has a history of substance abuse, or psychiatric comorbidities, the prescribing physician shall use a written agreement for treatment with the patient outlining patient responsibilities. This written agreement for treatment shall include:

(1) The patient's agreement to provide biological samples for urine/serum medical level screening when requested by the physician;

(2) The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost

prescriptions and early refills;

(3) Reasons for which drug therapy may be discontinued (e.g., violation of agreement);

(4) The requirement that all chronic pain management prescriptions are provided by a single prescriber or multidisciplinary pain clinic and dispensed by a single pharmacy or pharmacy system;

(5) The patient's agreement to not abuse alcohol or use other medically unauthorized substances;

(6) A written authorization for:

(a) The physician to release the agreement for treatment to local emergency departments, urgent care facilities, and pharmacies; and

(b) Other practitioners to report violations of the agreement back to the physician;

(7) A written authorization that the physician may notify the proper authorities if he or she has reason to believe the patient has engaged in illegal activity;

(8) Acknowledgment that a violation of the agreement may result in a tapering or discontinuation of the prescription;

(9) Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and

(10) Acknowledgment that if the patient violates the terms of the agreement, the violation and the physician's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

NEW SECTION

WAC 246-919-857 Periodic review. The physician shall periodically review the course of treatment for chronic noncancer pain, the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews shall take place at least every six months. However, for treatment of stable patients with chronic noncancer pain involving nonescalating daily dosages of forty milligrams of a morphine equivalent dose (MED) or less, periodic reviews shall take place at least annually.

(1) During the periodic review, the physician shall determine:

(a) Patient's compliance with any medication treatment plan;

(b) If pain, function, or quality of life have improved or diminished using objective evidence, considering any available information from family members or other caregivers; and

(c) If continuation or modification of medications for pain management treatment is necessary based on the physician's evaluation of progress towards treatment objectives.

(2) The physician shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory. The physician shall consider tapering, changing,

or discontinuing treatment when:

- (a) Function or pain does not improve after a trial period;
- (b) There is evidence of significant adverse effects;
- (c) Other treatment modalities are indicated; or
- (d) There is evidence of misuse, addiction, or diversion.

(3) The physician should periodically review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The physician should periodically review any relevant information from a pharmacist provided to the physician.

NEW SECTION

WAC 246-919-858 Long-acting opioids, including methadone.

Long-acting opioids, including methadone, should only be prescribed by a physician who is familiar with its risks and use, and who is prepared to conduct the necessary careful monitoring. Special attention should be given to patients who are initiating such treatment. The physician prescribing long-acting opioids or methadone should have a one-time (lifetime) completion of at least four hours of continuing education relating to this topic.

NEW SECTION

WAC 246-919-859 Episodic care.

(1) When evaluating patients for episodic care, such as emergency or urgent care, the physician should review any available prescription monitoring program, emergency department-based information exchange, or other tracking system.

(2) Episodic care practitioners should avoid providing opioids for chronic pain management. However, if opioids are provided, the practitioner should limit the use of opioids for a chronic noncancer pain patient to the minimum amount necessary to control the pain until the patient can receive care from a primary care practitioner.

(3) Prescriptions for opioids written by an episodic care practitioner shall include indications for use or the International Classification of Diseases (ICD) code and shall be written to require photo identification of the person picking up the prescription in order to fill.

(4) If a patient has signed a written agreement for treatment and has provided a written authorization to release the agreement under WAC 246-919-856(6) to episodic care practitioners, then the episodic care practitioner should report known violations of the

agreement back to the patient's treatment practitioner who provided the agreement for treatment.

NEW SECTION

WAC 246-919-860 Consultation--Recommendations and requirements. (1) The physician shall consider, and document the consideration, referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. Special attention should be given to those chronic noncancer pain patients who are under eighteen years of age, or who are at risk for medication misuse, abuse, or diversion. The management of pain in patients with a history of substance abuse or with comorbid psychiatric disorders may require extra care, monitoring, documentation, and consultation with, or referral to, an expert in the management of such patients.

(2) The mandatory consultation threshold for adults is one hundred twenty milligrams morphine equivalent dose (MED) (oral). In the event a physician prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED (orally) per day, a consultation with a pain management specialist as described in WAC 246-919-863 is required, unless the consultation is exempted under WAC 246-919-861 or 246-919-862. Great caution should be used when prescribing opioids to children with chronic noncancer pain and appropriate referrals to a specialist is encouraged.

(a) The mandatory consultation shall consist of at least one of the following:

(i) An office visit with the patient and the pain management specialist;

(ii) A telephone consultation between the pain management specialist and the physician;

(iii) An electronic consultation between the pain management specialist and the physician; or

(iv) An audio-visual evaluation conducted by the pain management specialist remotely, where the patient is present with either the physician or a licensed health care practitioner designated by the physician or the pain management specialist.

(b) A physician shall document each mandatory consultation with the pain management specialist. Any written record of the consultation by the pain management specialist shall be maintained as a patient record by the specialist. If the specialist provides a written record of the consultation to the physician, the physician shall maintain it as part of the patient record.

(3) Nothing in this chapter shall limit any person's ability to contractually require a consultation with a pain management specialist at any time. For the purposes of WAC 246-919-850 through 246-919-863, "person" means an individual, a trust or

estate, a firm, a partnership, a corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

NEW SECTION

WAC 246-919-861 Consultation--Exemptions for exigent and special circumstances. A physician is not required to consult with a pain management specialist as described in WAC 246-919-863 when he or she has documented adherence to all standards of practice as defined in WAC 246-919-850 through 246-919-863 and when any one or more of the following conditions apply:

- (1) The patient is following a tapering schedule;
- (2) The patient requires treatment for acute pain which may or may not include hospitalization, requiring a temporary escalation in opioid dosage, with expected return to or below their baseline dosage level; or
- (3) The physician documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above one hundred twenty milligrams morphine equivalent dose (MED) per day without first obtaining a consultation; or
- (4) The physician documents the patient's pain and function is stable and the patient is on a nonescalating dosage of opioids.

NEW SECTION

WAC 246-919-862 Consultation--Exemptions for the physician. The physician is exempt from the consultation requirement in WAC 246-919-860 if one or more of the following qualifications are met:

- (1) The physician is a pain management specialist under WAC 246-919-863; or
- (2) The physician has successfully completed, within the last two years, a minimum of twelve (Category I) continuing education hours on chronic pain management with at least two of these hours dedicated to long acting opioids; or
- (3) The physician is a pain management practitioner working in a multidisciplinary chronic pain treatment center, or a multidisciplinary academic research facility; or
- (4) The physician has a minimum three years of clinical experience in a chronic pain management setting, and at least thirty percent of his or her current practice is the direct provision of pain management care.

NEW SECTION

WAC 246-919-863 Pain management specialist. A pain management specialist shall meet one or more of the following qualifications:

(1) If a physician or osteopathic physician:

(a) Board certified or board eligible by an American Board of Medical Specialties-approved board (ABMS) or by the American Osteopathic Association (AOA) in physical medicine and rehabilitation, rehabilitation medicine, neurology, rheumatology, or anesthesiology; or

(b) Has a subspecialty certificate in pain medicine by an ABMS-approved board; or

(c) Has a certification of added qualification in pain management by the AOA; or

(d) A minimum of three years of clinical experience in a chronic pain management care setting; and

(i) Credentialed in pain management by an entity approved by the Washington state medical quality assurance commission for physicians or the Washington state board of osteopathic medicine and surgery for osteopathic physicians; and

(ii) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years for physicians or three years for osteopathic physicians; and

(iii) At least thirty percent of the physician's or osteopathic physician's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

(2) If a dentist: Board certified or board eligible in oral medicine or orofacial pain by the American Board of Oral Medicine or the American Board of Orofacial Pain.

(3) If an advanced registered nurse practitioner (ARNP):

(a) A minimum of three years of clinical experience in a chronic pain management care setting;

(b) Credentialed in pain management by the Washington state nursing care quality assurance commission-approved national professional association, pain association, or other credentialing entity;

(c) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and

(d) At least thirty percent of the ARNP's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

(4) If a podiatric physician:

(a) Board certified or board eligible in a specialty that includes a focus on pain management by the American Board of Podiatric Surgery, the American Board of Podiatric Orthopedics and Primary Podiatric Medicine, or other accredited certifying board as

approved by the Washington state podiatric medical board; or

(b) A minimum of three years of clinical experience in a chronic pain management care setting; and

(c) Credentialed in pain management by the Washington state podiatric medical board-approved national professional association, pain association, or other credentialing entity; and

(d) Successful completion of a minimum of at least eighteen hours of continuing education in pain management during the past two years, and at least thirty percent of the podiatric physician's current practice is the direct provision of pain management care.

Pain Management

NEW SECTION

WAC 246-918-800 Pain management--Intent. These rules govern the use of opioids in the treatment of patients for chronic noncancer pain.

Nothing in these rules in any way restricts the current scope of practice of physician assistants as set forth in chapters 18.71A and 18.57A RCW and the working agreements between the physician and physician assistant, which may include pain management.

The Washington state medical quality assurance commission (commission) recognizes that principles of quality medical practice dictate that the people of the state of Washington have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this rule, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The commission encourages physician assistants to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physician assistants should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this rule has been developed to clarify the commission's position on pain control, particularly as related to the use of controlled substances, to alleviate physician assistant uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from a physician assistant's lack of knowledge about pain management. Fears of investigation or sanction by federal, state, and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician assistant's responsibility. As such, the commission will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain

cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The commission recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or noncancer origins. The commission will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and nonpharmacologic modalities according to the judgment of the physician assistant. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physician assistants should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The commission is obligated under the laws of the state of Washington to protect the public health and safety. The commission recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the commission expects that physician assistants incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physician assistants should not fear disciplinary action from the commission for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The commission will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician assistant-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The commission will judge the validity of the physician assistant's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

These rules are designed to assist practitioners in providing appropriate medical care for patients. They are not inflexible rules or rigid practice requirements and are not intended, nor should they be used, to establish a legal standard of care outside the context of the medical quality assurance committee's jurisdiction.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner based on all the circumstances presented. Thus, an approach that differs from the rules, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the rules when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of these rules. However, a practitioner who employs an approach substantially different from these rules is advised to document in the patient record information sufficient to justify the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these rules will not assure an accurate diagnosis or a successful outcome. The sole purpose of these rules is to assist practitioners in following a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

NEW SECTION

WAC 246-918-801 Exclusions. The rules adopted under WAC 246-918-800 through 246-918-813 do not apply:

(1) To the provision of palliative, hospice, or other end-of-life care; or

(2) To the management of acute pain caused by an injury or surgical procedure.

NEW SECTION

WAC 246-918-802 Definitions. The definitions in this section apply in WAC 246-918-800 through 246-918-813 unless the context clearly requires otherwise.

(1) "Acute pain" means the normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and

disease. It is generally time-limited, often less than three months in duration, and usually less than six months.

(2) "Addiction" means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include:

- (a) Impaired control over drug use;
- (b) Craving;
- (c) Compulsive use; or
- (d) Continued use despite harm.

(3) "Chronic noncancer pain" means a state in which noncancer pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

(4) "Comorbidity" means a preexisting or coexisting physical or psychiatric disease or condition.

(5) "Episodic care" means medical care provided by a practitioner other than the designated primary care practitioner in the acute care setting, for example, urgent care or emergency department.

(6) "Hospice" means a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less. Hospice involves an interdisciplinary approach to provide health care, pain management, and emotional and spiritual support. The emphasis is on comfort, quality of life and patient and family support. Hospice can be provided in the patient's home as well as freestanding hospice facilities, hospitals, nursing homes, or other long-term care facilities.

(7) "Morphine equivalent dose" means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.

(8) "Multidisciplinary pain clinic" means a clinic or office that provides comprehensive pain management and includes care provided by multiple available disciplines or treatment modalities, for example, medical care through physicians, physician assistants, osteopathic physicians, osteopathic physician assistants, advanced registered nurse practitioners, and physical therapy, occupational therapy, or other complementary therapies.

(9) "Palliative" means care that improves the quality of life of patients and their families facing life-threatening illness. With palliative care particular attention is given to the prevention, assessment, and treatment of pain and other symptoms, and to the provision of psychological, spiritual, and emotional support.

NEW SECTION

WAC 246-918-803 Patient evaluation. The physician assistant shall obtain, evaluate, and document the patient's health history and physical examination in the health record prior to treating for chronic noncancer pain.

- (1) The patient's health history shall include:
 - (a) Current and past treatments for pain;
 - (b) Comorbidities; and
 - (c) Any substance abuse.
- (2) The patient's health history should include:
 - (a) A review of any available prescription monitoring program or emergency department-based information exchange; and
 - (b) Any relevant information from a pharmacist provided to the physician assistant.
- (3) The initial patient evaluation shall include:
 - (a) Physical examination;
 - (b) The nature and intensity of the pain;
 - (c) The effect of the pain on physical and psychological function;
 - (d) Medications including indication(s), date, type, dosage, and quantity prescribed;
 - (e) A risk screening of the patient for potential comorbidities and risk factors using an appropriate screening tool. The screening should address:
 - (i) History of addiction;
 - (ii) Abuse or aberrant behavior regarding opioid use;
 - (iii) Psychiatric conditions;
 - (iv) Regular concomitant use of benzodiazepines, alcohol, or other central nervous system medications;
 - (v) Poorly controlled depression or anxiety;
 - (vi) Evidence or risk of significant adverse events, including falls or fractures;
 - (vii) Receipt of opioids from more than one prescribing practitioner or practitioner group;
 - (viii) Repeated visits to emergency departments seeking opioids;
 - (ix) History of sleep apnea or other respiratory risk factors;
 - (x) Possible or current pregnancy; and
 - (xi) History of allergies or intolerances.
- (4) The initial patient evaluation should include:
 - (a) Any available diagnostic, therapeutic, and laboratory results; and
 - (b) Any available consultations.
- (5) The health record shall be maintained in an accessible manner, readily available for review, and should include:
 - (a) The diagnosis, treatment plan, and objectives;
 - (b) Documentation of the presence of one or more recognized indications for the use of pain medication;
 - (c) Documentation of any medication prescribed;
 - (d) Results of periodic reviews;
 - (e) Any written agreements for treatment between the patient and the physician assistant; and

(f) The physician assistant's instructions to the patient.

NEW SECTION

WAC 246-918-804 Treatment plan. (1) The written treatment plan shall state the objectives that will be used to determine treatment success and shall include, at a minimum:

- (a) Any change in pain relief;
- (b) Any change in physical and psychosocial function; and
- (c) Additional diagnostic evaluations or other planned treatments.

(2) After treatment begins the physician assistant should adjust drug therapy to the individual health needs of the patient. The physician assistant shall include indications for medication use on the prescription and require photo identification of the person picking up the prescription in order to fill. The physician assistant shall advise the patient that it is the patient's responsibility to safeguard all medications and keep them in a secure location.

(3) Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

NEW SECTION

WAC 246-918-805 Informed consent. The physician assistant shall discuss the risks and benefits of treatment options with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without health care decision-making capacity.

NEW SECTION

WAC 246-918-806 Written agreement for treatment. Chronic noncancer pain patients should receive all chronic pain management prescriptions from one physician assistant and one pharmacy whenever possible. If the patient is at high risk for medication abuse, or has a history of substance abuse, or psychiatric comorbidities, the prescribing physician assistant shall use a

written agreement for treatment with the patient outlining patient responsibilities. This written agreement for treatment shall include:

(1) The patient's agreement to provide biological samples for urine/serum medical level screening when requested by the physician assistant;

(2) The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;

(3) Reasons for which drug therapy may be discontinued (e.g., violation of agreement);

(4) The requirement that all chronic pain management prescriptions are provided by a single prescriber or multidisciplinary pain clinic and dispensed by a single pharmacy or pharmacy system;

(5) The patient's agreement to not abuse alcohol or use other medically unauthorized substances;

(6) A written authorization for:

(a) The physician assistant to release the agreement for treatment to local emergency departments, urgent care facilities, and pharmacies; and

(b) Other practitioners to report violations of the agreement back to the physician assistant;

(7) A written authorization that the physician assistant may notify the proper authorities if he or she has reason to believe the patient has engaged in illegal activity;

(8) Acknowledgment that a violation of the agreement may result in a tapering or discontinuation of the prescription;

(9) Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and

(10) Acknowledgment that if the patient violates the terms of the agreement, the violation and the physician assistant's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

NEW SECTION

WAC 246-918-807 Periodic review. The physician assistant shall periodically review the course of treatment for chronic noncancer pain, the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews shall take place at least every six months. However, for treatment of stable patients with chronic noncancer pain involving nonescalating daily dosages of forty milligrams of a morphine equivalent dose (MED) or less, periodic reviews shall take place at least annually.

(1) During the periodic review, the physician assistant shall determine:

(a) Patient's compliance with any medication treatment plan;

(b) If pain, function, or quality of life have improved or diminished using objective evidence, considering any available information from family members or other caregivers; and

(c) If continuation or modification of medications for pain management treatment is necessary based on the physician assistant's evaluation of progress towards treatment objectives.

(2) The physician assistant shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory. The physician assistant shall consider tapering, changing, or discontinuing treatment when:

(a) Function or pain does not improve after a trial period;

(b) There is evidence of significant adverse effects;

(c) Other treatment modalities are indicated; or

(d) There is evidence of misuse, addiction, or diversion.

(3) The physician assistant should periodically review information from any available prescription monitoring program or emergency department-based information exchange.

(4) The physician assistant should periodically review any relevant information from a pharmacist provided to the physician assistant.

NEW SECTION

WAC 246-918-808 Long-acting opioids, including methadone.

Long-acting opioids, including methadone, should only be prescribed by a physician assistant who is familiar with its risks and use, and who is prepared to conduct the necessary careful monitoring. Special attention should be given to patients who are initiating such treatment. A physician assistant prescribing long-acting opioids or methadone should have a one-time (lifetime) completion of at least four continuing education hours relating to this topic.

NEW SECTION

WAC 246-918-809 Episodic care. (1) When evaluating patients for episodic care, such as emergency or urgent care, the physician assistant should review any available prescription monitoring program, emergency department-based information exchange, or other tracking system.

(2) Episodic care practitioners should avoid providing opioids for chronic pain management. However, if opioids are provided, the practitioner should limit the use of opioids for a chronic noncancer pain patient to the minimum amount necessary to control

the pain until the patient can receive care from a primary care practitioner.

(3) Prescriptions for opioids written by an episodic care practitioner shall include indications for use or the International Classification of Diseases (ICD) code and shall be written to require photo identification of the person picking up the prescription in order to fill.

(4) If a patient has signed a written agreement for treatment and has provided a written authorization to release the agreement under WAC 246-918-806(6) to episodic care practitioners, then the episodic care practitioner should report known violations of the agreement back to the patient's treatment practitioner who provided the agreement for treatment.

NEW SECTION

WAC 246-918-810 Consultation--Recommendations and requirements. (1) The physician assistant shall consider, and document the consideration, referring the patient for additional evaluation and treatment as needed to achieve treatment objectives. Special attention should be given to those chronic noncancer pain patients who are under eighteen years of age, or who are at risk for medication misuse, abuse, or diversion. The management of pain in patients with a history of substance abuse or with comorbid psychiatric disorders may require extra care, monitoring, documentation, and consultation with, or referral to, an expert in the management of such patients.

(2) The mandatory consultation threshold for adults is one hundred twenty milligrams morphine equivalent dose (MED)(oral). In the event a practitioner prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED (orally) per day, a consultation with a pain management specialist as described in WAC 246-918-813 is required, unless the consultation is exempted under WAC 246-918-811 or 246-918-812. Great caution should be used when prescribing opioids to children with chronic noncancer pain and appropriate referrals to a specialist is encouraged.

(a) The mandatory consultation shall consist of at least one of the following:

(i) An office visit with the patient and the pain management specialist;

(ii) A telephone consultation between the pain management specialist and the physician assistant;

(iii) An electronic consultation between the pain management specialist and the physician assistant; or

(iv) An audio-visual evaluation conducted by the pain management specialist remotely, where the patient is present with either the physician assistant or a licensed health care

practitioner designated by the physician assistant or the pain management specialist.

(b) A physician assistant shall document each mandatory consultation with the pain management specialist. Any written record of the consultation by the pain management specialist shall be maintained as a patient record by the specialist. If the specialist provides a written record of the consultation to the physician assistant, the physician assistant shall maintain it as part of the patient record.

(3) Nothing in this chapter shall limit any person's ability to contractually require a consultation with a pain management specialist at any time. For the purposes of WAC 246-918-800 through 246-918-813, "person" means an individual, a trust or estate, a firm, a partnership, a corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

NEW SECTION

WAC 246-918-811 Consultation--Exemptions for exigent and special circumstances. A physician assistant is not required to consult with a pain management specialist as described in WAC 246-918-813 when he or she has documented adherence to all standards of practice as defined in WAC 246-918-800 through 246-918-813 when any one or more of the following conditions apply:

- (1) The patient is following a tapering schedule;
- (2) The patient requires treatment for acute pain which may or may not include hospitalization, requiring a temporary escalation in opioid dosage, with expected return to or below their baseline dosage level;
- (3) The physician assistant documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above one hundred twenty milligrams morphine equivalent dose (MED) per day without first obtaining a consultation; or
- (4) The physician assistant documents that the patient's pain and function is stable and that the patient is on a nonescalating dosage of opioids.

NEW SECTION

WAC 246-918-812 Consultation--Exemptions for the physician assistant. The physician assistant is exempt from the consultation requirement in WAC 246-918-810 if one or more of the following qualifications are met:

(1) The sponsoring physician is a pain management specialist under WAC 246-918-813; or

(2) The sponsoring physician and the physician assistant has successfully completed, within the last two years, a minimum of twelve continuing education hours (Category 1 for physicians) on chronic pain management, with at least two of these hours dedicated to long-acting opioids; or

(3) The physician assistant is a pain management practitioner working in a multidisciplinary chronic pain treatment center, or a multidisciplinary academic research facility.

NEW SECTION

WAC 246-918-813 Pain management specialist. A pain management specialist shall meet one or more of the following qualifications:

(1) If a physician or osteopathic physician:

(a) Board certified or board eligible by an American Board of Medical Specialties-approved board (ABMS) or by the American Osteopathic Association (AOA) in physical medicine and rehabilitation, rehabilitation medicine, neurology, rheumatology, or anesthesiology; or

(b) Has a subspecialty certificate in pain medicine by an ABMS-approved board; or

(c) Has a certification of added qualification in pain management by the AOA; or

(d) A minimum of three years of clinical experience in a chronic pain management care setting; and

(i) Credentialed in pain management by an entity approved by the Washington state medical quality assurance commission for physicians or the Washington state board of osteopathic medicine and surgery for osteopathic physicians; and

(ii) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years for physicians or three years for osteopathic physicians; and

(iii) At least thirty percent of the physician's or osteopathic physician's current practice is the direct provision of pain management care, or is in a multidisciplinary pain clinic.

(2) If a dentist: Board certified or board eligible in oral medicine or orofacial pain by the American Board of Oral Medicine or the American Board of Orofacial Pain.

(3) If an advanced registered nurse practitioner (ARNP):

(a) A minimum of three years of clinical experience in a chronic pain management care setting;

(b) Credentialed in pain management by the Washington state nursing care quality assurance commission-approved national professional association, pain association, or other credentialing entity;

(c) Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and

(d) At least thirty percent of the ARNP's current practice is the direct provision of pain management care, or is in a multidisciplinary pain clinic.

(4) If a podiatric physician:

(a) Board certified or board eligible in a specialty that includes a focus on pain management by the American Board of Podiatric Surgery, the American Board of Podiatric Orthopedics and Primary Podiatric Medicine, or other accredited certifying board as approved by the Washington state podiatric medical board; or

(b) A minimum of three years of clinical experience in a chronic pain management care setting; and

(c) Credentialed in pain management by the Washington state podiatric medical board-approved national professional association, pain association, or other credentialing entity; and

(d) Successful completion of a minimum of at least eighteen hours of continuing education in pain management during the past two years, and at least thirty percent of the podiatric physician's current practice is the direct provision of pain management care.

